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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,135	09/27/2001	Walter H. Gunzburg	2316.1002-001	2027

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DURHAM, NC 27707

EXAMINER

HILL, MYRON G

ART UNIT PAPER NUMBER

1648

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

<b>Application No.</b> 09/965,135	<b>Applicant(s)</b> GUNZBURG ET AL.	
<b>Examiner</b> Myron G. Hill	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 28 October 2005.
- 2a)  This action is **FINAL**.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 5,8-17 and 22-25 is/are pending in the application.
  - 4a) Of the above claim(s) 9-17 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 5,8 and 22-25 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.
  - Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  - Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All b)  Some \* c)  None of:
    - 1.  Certified copies of the priority documents have been received.
    - 2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    - 3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_

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### **DETAILED ACTION**

The Examiner and/or Art Unit of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Hill.

This action is in response the paper filed 28 October 2005.

Claims 5, 8, and 22-25 are under consideration.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5, 8, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunzburg *et al.* (Nature. 1993; 364 (July 8): 154- 1 58), Gilboa (US 5,658,775) and Vile *et al.* (Cancer Research. 1993; 53 (5): 962-7).

The claims are drawn to a retrovirus vector that is capable of undergoing promoter conversion and is replication defective. The retrovirus comprises, 5' to 3': U3-R-U5, a first coding sequence encoding a therapeutic peptide, a second sequence encoding a peptide with Sag activity that is linked to a promoter that is active in B and/or T cells and a 3'LTR comprising a partially or completely deleted U3 region that

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comprises a tissue-specific promoter that regulates the expression of the first coding sequence, followed by R-U5.

Applicant argues that the combined references do not teach or suggest the claimed vector, that the vector is not self-inactivating, that the body of the vector contains two coding sequences, that the first is promoterless and the second encodes a SAG and is under the control of a T or B cell specific promoter, that none of the Gunzberg vectors have a 3 prime U3 deletion, that the '775 patent does not have a unique restriction site into which is inserted regulatory elements and the promoter is operably linked to the sequence itself, that the Office must consider the references as a whole, and that in summary, the two references do not support the rejection of the claims. Additionally, applicant comments on the previous reasoning in the last Office action.

Applicant's arguments have been fully considered and not found persuasive.

It is not clear in Applicant's argument how the vector can be both replication defective and not self inactivating. The limitation "not self inactivating" is not in the claims, as such. Applicant is requested to point to the structural limitation recited in the claim that specifies this combination of activity.

One of ordinary skill in the art at the time of invention would have been familiar with vector construction and manipulation. Gunzburg teaches that a promoterless coding sequence can be expressed from a vector and the promoter is functional in B lineage cells (Figure 3). One of ordinary skill in the art at the time of invention would

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have known that vectors can express two genes. One of ordinary skill in the art at the time of invention would have wanted to express both the therapeutic gene and the SAG gene to get the benefits of T cell activation (Gunzburg, page 154, column 1). The vector of '775 allows for insertion of a promoter in the 3 prime U3 region (column 9, lines 1-4 and column 8, lines 43-45). The '775 teaches the benefits of a SIN vector and that it uses a deletion in the 3 prime U3 region. One of ordinary skill in the art at the time of invention would have known that making the virus defective in this way would change the existing promoter in the 5 prime U3 region in the vector of Gunzburg. One of ordinary skill in the art at the time of invention would have known that promoters would have to be included in the vector in order to express the genes of interest and know that the the promoter of Gunzburg would have to be replaced when the promoter conversion of '775 is used and '775 teaches how to get a promoter into the 5 prime U3 to transcribe genes of interest (col 9, lines 1-4). One of ordinary skill in the art at the time of invention would have known about cell specific promoters and construction of vectors for gene therapy, including the use of unique restriction sites to facilitate the insertion/deletion of elements when cloning. Gunzburg also teaches that there are tissue specific promoters (Figure 3). One of ordinary skill in the art at the time of invention would have known that the SAG gene of Gunzburg would need a promoter/regulatory sequences of its own because after promoter conversion occurs the native promoter and splicing elements in MMTV would be deleted. Lastly, the rejection is based on three references not two as asserted by Applicant.

Thus, the rejection is maintained.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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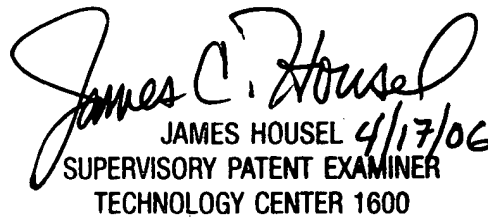
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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Myron G. Hill  
Patent Examiner  
30 March 2006



JAMES HOUSEL 4/17/06  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600